

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC,

Plaintiff,

v.

HETERO USA, INC., HETERO LABS LTD., and
HETERO LABS LTD. UNIT-VI,

Defendants.

C.A. No. 1:24-cv-01025-JLH

**DEFENDANTS HETERO USA, INC., HETERO LABS LTD., AND
HETERO LABS LTD. UNIT-VI'S STATEMENT OF UNDISPUTED FACTS IN
SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT**

Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI (collectively, "Hetero" or "Defendants") submit the following statement of undisputed facts in support of their Motion for Summary Judgment.

1. U.S. Patent No. 10,993,952 ("the '952 patent"), titled "Stable ready to Use Cyclophosphamide Liquid Formulations," was issued by the U.S. Patent and Trademark Office on May 4, 2021. D.I. 1-1. The patent contains four claims directed to formulations of cyclophosphamide, which all require a stable liquid parenteral formulation. *Id.* at Abstract ("The present invention relates to stable ready to use liquid formulations of Cyclophosphamide for parenteral use."). Claim 1 of the '952 patent, which is the only independent claim, requires in the preamble "[a] stable liquid parenteral formulation." *Id.* at Claim 1. Claims 2-4 depend from claim 1 and therefore similarly require a stable liquid parenteral formulation. *Id.* at Claims 2-4.

2. Plaintiffs Ingenus Pharmaceuticals, LLC ("Ingenus") and Leiutis Pharmaceuticals, LLP asserted infringement of the '952 patent against Nexus Pharmaceuticals, Inc. ("Nexus") on June 1, 2022, in the Northern District of Illinois. Exhibit 1, Complaint for

Patent Infringement, *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 1:22-cv-02868 (N.D. Ill.), (D.I. 1).

3. On December 6, 2024, Nexus moved for summary judgment on the grounds that all claims of the '952 patent were invalid as indefinite. Exhibit 2, Docket, *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 1:22-cv-02868 (N.D. Ill.), D.I. 132-135 (Defendant's Motion for Summary Judgment – filed under seal).

4. The issue of the invalidity of the '952 patent was determined by a final judgment in the Northern District of Illinois. On May 9, 2025, the court issued a Memorandum Opinion and Order finding that all claims of the '952 patent were invalid. Exhibit 3, Memorandum Opinion and Order, *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 1:22-cv-02868 (N.D. Ill.) (D.I. 215).

5. In the opinion, the court determined that the term “stable” is indefinite because that term “could be ascertained by different measures, those measures could yield different results, and neither intrinsic nor extrinsic evidence indicates which to use. The term is thus indefinite.” *Id.* at p. 12.

6. On the basis of its indefiniteness finding, the Northern District of Illinois entered final judgment of invalidity against Ingenus on May 9, 2025. Exhibit 4, Judgment in a Civil Case, *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 1:22-cv-02868 (N.D. Ill.) (D.I. 216).

7. The only issue in the Northern District of Illinois's summary judgment decision was whether the '952 patent was invalid because of indefiniteness of the term “stable.” Exhibit 3, Memorandum Opinion and Order at 18.

8. Ingenus filed a Notice of Appeal on June 2, 2025. Exhibit 5, Notice of Appeal,

Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc., Case No. 1:22-cv-02868 (N.D. Ill.) (D.I. 219).

9. In the Northern District of Illinois, Ingenus was represented by the same counsel as this case and fully briefed the issue of indefiniteness. Exhibit 2, Docket, p. 1 (counsel for Plaintiffs), D.I. 132-135 (Defendant’s Motion for Summary Judgment – filed under seal), D.I. 153-156 (Plaintiffs’ Opposition – filed under seal), D.I. 175-178 (Defendant’s Reply – filed under seal).

10. In its summary judgment opinion holding that the ‘952 patent is indefinite as a matter of law, the Northern District of Illinois considered the opinions of both parties’ experts. Exhibit 3, Memorandum Opinion and Order at pp. 6-11.

11. Ingenus sued Hetero on September 11, 2024, in this Court, alleging that Hetero infringed the ‘952 patent. ECF 1. In this litigation, Ingenus has asserted that Hetero infringes all the claims, claims 1-4, of the ‘952 patent. Exhibit 6, Plaintiffs’ Paragraph 4(a) Disclosures.

12. Hetero’s first supplemental invalidity contentions assert that the ‘952 patent is invalid because the term “stable” is indefinite. Exhibit 7, Defendants’ First Supplemental Invalidity Contentions, at pp. 45-47.

13. Hetero’s indefiniteness argument is the same as the argument adopted by the Northern District of Illinois in its summary judgment opinion. *Compare id*; Exhibit 3, Memorandum Opinion and Order at pp. 5-11.

14. Both the Northern District of Illinois’s ruling and Hetero’s invalidity defense are based on the indefiniteness of the term “stable.” *Id.* at p. 17.

15. The finding in the Northern District of Illinois applies to all the claims of the ‘952 patent asserted in both cases. *Id.*

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